REMARKS

Claims 63-85 are currently pending in this application, with claims 63 and 80-82 being independent claims. No new matter has been added.

Allowable Subject Matter

Applicant thanks the Examiner for indicating that claims 80-82 are allowed and that claims 69-71 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Interview with Examiner VanderVegt

Applicant respectfully thanks Examiner VanderVegt for conducting an interview with Applicant's representative. During the interview, Applicant's representative discussed the rejections of the outstanding Final Office Action, mailed from the United States Patent and Trademark Office on March 1, 2005. Ultimately, no conclusive agreement was reached.

Response to the Examiner's Summary of the Previous Informal Discussion

Applicant's representative apologizes for any misunderstanding of the subject matter the Examiner indicated would likely be allowable in the previous informal discussion held in regard to the Office Action mailed from the United States Patent and Trademark Office on July 23, 2004. However, Applicant's representative notes that the current claim set and the claim set previously under consideration are of different scope. In addition, for at least the reasons provided herein, Applicant did and continues to believe that the current and previous rejections do not apply to the current claims.

Rejections under 35 U.S.C. §112

The Examiner has rejected claims 63-68, 72-79 and 83-85 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant respectfully traverses the rejection. In order for this rejection to be applicable to the current claims, it must be shown that one of ordinary skill in the art would not recognize in the application a description of what is claimed. Applicant maintains that this has not been demonstrated. Applicant further maintains that the specification does indeed provide a description sufficient to demonstrate possession of the subject matter of the rejected claims.

The rejected claims are directed to antibodies and fragments thereof that bind human mannose binding lectin (MBL) and comprise a CDR3 from one of three deposited antibodies. The rejected claims are further directed to compositions comprising these antibodies and antibody fragments. The specification provides a sufficient description of this subject matter. For example, the specification describes, on page 3, lines 23-27, MBL-binding peptides that have a MBL-binding CDR3 region and provides that MBL-binding peptides can be antibodies or antibody fragments. On page 4, line 24 through page 5, line 24, the specification again teaches that MBL-binding peptides can have a CDR3 from the three deposited antibodies, and that the MBL-binding peptides can be intact soluble monoclonal antibodies, humanized antibodies or antibody fragments. On page 18, lines 28-31, the instant specification teaches that the CDR regions, and in particular the CDR3 region, can be incorporated into other antibodies. The CDR regions, as are the sequences of these regions, are inherently provided by the deposit of Applicant's three monoclonal antibodies as described, for example, on page 19, lines 6-22. Further, humanized monoclonal antibodies that contain a CDR3 region from the deposited antibodies and a description of how they can be produced are provided on page 21, line 4 through page 23, line 2. Antibody fragments, including humanized monoclonal antibody fragments are described on page 25, line 3 through page 26, line 29.

The Examiner has argued that Applicant has only demonstrated possession of the three deposited monoclonal antibodies and not the genus of the anti-MBL antibodies of the claims. Applicant disagrees. With at least the above-described support found in the instant specification, one of ordinary skill in the art would clearly recognize a description of the claimed subject matter and not merely the three deposited monoclonal antibodies. Applicant maintains that the specification provides antibodies and antibody fragments that bind MBL and contain a CDR3 of the deposited antibodies. The specification further provides all of the CDR regions of the deposited monoclonal antibodies, the sequences of which are inherently disclosed by the deposit

of the antibodies. Enzo Biochem v. Gen-Probe, 323 F.3d 956, 964 (Fed. Cir. 2002). Further, although not necessary, examples of intact monoclonal antibodies are provided as is a description of a methodology to produce humanized monoclonal antibodies containing a CDR3 of the deposited monoclonal antibodies.

The Examiner has also argued that the claims read upon any mannose-binding lectin (MBL)-binding peptide that comprise a CDR3 of one of the three deposited monoclonal antibodies. Applicant wishes to note, however, that the rejected claims read upon human MBL-binding antibodies and antibody fragments thereof that comprise a CDR3 of one of the three deposited monoclonal antibodies.

Based on the above, Applicant maintains that the description provided by the instant disclosure adequately describes the claimed invention such that one or ordinary skill in the art would recognize that Applicant, at that time the instant application was filed, had possession of the claimed invention. It has not been demonstrated by a preponderance of the evidence why a person skilled in the art would not recognize in Applicant's disclosure a description of the subject matter of the claims.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 63-68, 72-79 and 83-85 under 35 U.S.C. §112, first paragraph, as the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant respectfully traverses the rejection. The Examiner argues that Janeway et al. treat all of the CDRs equally and show that the three CDRs and intervening sequences all contribute to forming the binding site. Applicant, however, disagrees with the Examiner's conclusion of non-enablement based on these teachings. Janeway et al. do not demonstrate that one of ordinary skill in the art would not be able to make MBL-binding antibodies and antibody fragments thereof that contain a CDR3 region as provided by Applicant. The teaching that other CDRs are involved in antigen binding does not teach that an antibody with one or a combination of CDRs would necessarily fail to bind an antigen specific to the antibody from which the CDR(s) were obtained. In addition, that other CDRs are involved in the antigen binding of a

complete antibody is not a teaching that fragments of the antibody, such as fragments as short as a single CDR would also necessarily fail to bind its specific antigen. Applicant maintains that one of ordinary skill in the art would reasonably expect to be able to produce the antibodies and antibody fragments of Applicant's claims.

In support of Applicant's assertion, the Examiner is again referred to the references previously provided by Applicant (Laune, D., et al. *The Journal of Biological Chemistry*. Vol. 272, No. 49, pp. 30937-30944, 1997; Monnet, C., et al., *The Journal of Biological Chemistry*. Vol. 274, No. 6, pp. 3789-3796, 1999; Taub, R., et al., *The Journal of Biological Chemistry*. Vol. 264, No. 1, pp. 259-265, 1989; Igarashi, K., et al., *J Biochem (Tokyo)*. Vol. 117, No. 2, pp. 452-7, 1995.) As argued previously, these references demonstrate that antigen-binding synthetic peptides, based on the amino acid sequences of the V_H and V_L domains of an antibody and which include peptides that contain one or more CDR residues, can be produced. In fact, peptides containing the CDR3 region of an antibody have been shown to be capable of binding antigen. Applicant maintains that the teachings of the references confirm that all of the CDRs are not necessary for binding antigen as the Examiner has asserted in regard to Janeway et al. In addition, the teachings of the references support the notion that one of ordinary skill in the art is enabled to produce antibody fragments, which are encompassed by the scope of Applicant's claims.

Furthermore, Applicant notes that the Examiner has acknowledged that antibodies and antibody fragments within the scope of the rejected claims can be made. The Examiner, during the latest interview with Applicant's representative, acknowledged that some combinations of CDRs could produce antibodies that would bind antigen. The Examiner also acknowledged, in the Final Office Action on page 4, that "...a peptide consisting of the disclosed CDR3s may very well bind to MBL...". Although the Examiner contends that Applicant has not demonstrated that longer peptides will also bind MBL, it is not sufficient to assert that non-working embodiments may exist to sustain the rejection. The fact that inactive peptides might be made is irrelevant to the issue of whether the disclosure enables one of ordinary skill in the art to make antibodies or fragments thereof, containing a CDR3 of the deposited antibodies, which do bind to human MBL. Again, in In re Marzocchi, the courts found that even if claims are directed to non-working embodiments, it is not sufficient to assert a rejection for lack of enablement when

avoiding such embodiments would be within the level of ordinary skill in the art. In re Marzocchi, 439 F.2d 220, 224 (CCPA 1971). Applicant maintains that this is the case.

As argued previously, the level of skill in the relevant art of the biological sciences and antibody production is very high, and the highly skilled artisan is reasonably able to produce the antibodies or antibody fragments of the rejected claims based on the guidance provided in Applicant's specification and the knowledge of those in the art. Such a reasonable expectation is sufficient to satisfy the enablement requirement. Applicant maintains that one of ordinary skill in the art would be able to make an antibody or fragment thereof that contains a CDR3 region of the deposited antibodies and determine the ability of the antibody or fragment thereof to bind human MBL using only routine methods known in the art and the teachings of the specification. The sequences and various fragments of the antibodies are inherently provided by the deposit of the antibodies. Enzo Biochem v. Gen-Probe, 323 F.3d 956, 964 (Fed. Cir. 2002). With the deposited antibodies, one of skill in the art could easily produce the CDR regions, the antigen binding fragments of the antibodies or the whole antibodies themselves to make antibodies or fragments thereof that fall within the scope of the claims. Additionally, one of ordinary skill in the art would use only routine experimentation to produce other antibodies or fragments thereof that contain a CDR3 region of the deposited antibodies. For instance, humanized monoclonal antibodies that contain a CDR3 region from the deposited antibodies can be produced using the methods provided on page 21, line 4 through page 23, line 2 of the specification. Other antibodies can be similarly produced. Furthermore, the function of the antibodies or fragments thereof can be assessed, for example, with binding assays and competition assays, such as those provided on page 16 of the specification.

Finally, the Examiner has argued that the specification is not enabling for making peptides comprising conservative substitutions of the CDR regions of the deposited monoclonal antibodies, in part because the Examiner maintains that the sequence of the monoclonal antibodies are not disclosed. While Applicant disagrees with the Examiner and maintains that the specification is sufficiently enabling for one of ordinary skill in the art to produce conservatively substituted versions of the CDRs provided and to use them to produce MBL-binding peptides, Applicant notes that the claims are directed to antibodies and antibody fragments thereof and no longer recite the term "conservative substitution". Applicant also notes

that the sequence of the monoclonal antibodies is inherently disclosed by their deposit. Enzo Biochem v. Gen-Probe, 323 F.3d 956, 964 (Fed. Cir. 2002).

Therefore, the sequences of the antibodies and their CDRs have been disclosed, guidance has been provided for producing a number of antibodies and antibody fragments containing a CDR3 of the deposited antibodies, and it is irrelevant if some non-working products are encompassed by the claims since the disclosure enables one of ordinary skill in the art to make working products.

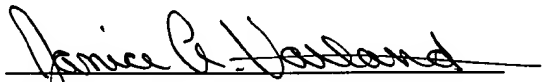
Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the application in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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